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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/985,820	11/06/2001	David Vale	08157.0014	4546
22852	7590	07/12/2005	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			HO, UYEN T	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 07/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 09/985,820	<b>Applicant(s)</b> VALE ET AL.	
	<b>Examiner</b> (Jackie) Tan-Uyen T. Ho	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 April 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-41 and 48-63 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 32-41 and 63 is/are allowed.
- 6) ☒ Claim(s) 1-31 and 48-62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Response to Arguments*

1. Applicant's arguments filed 4/18/05 have been fully considered but they are not persuasive. In response to applicant's argument that Ding reference is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Ding reference is in the field of applicant's endeavor, the thickness of the coating on a medical device. Applicant argues that the thickness of the coating of Ding reference relates particularly to the use of a drug-releasing type coatings while the thickness coating of present invention enables the filter body to have a low profile but still retain good memory, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Ding reference is a teaching reference, the main reference which is Ambrisco et al. disclose all the limitations of the claims including a drug coating on a filter but fails to suggest the thickness as claimed. Ding reference does not have to disclose such a drug-releasing type of coating in association with a collapsible filter element since it is only a teaching reference suggesting the thickness of the drug coating on a medical device.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-31, 48-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ambrisco et al. (6,007,557) in view of Ding et al. (5,879,697). Ambrisco et al. disclose a filter system as claimed and suggest the filter membrane may be coated with a non-thrombogenic material for example Heparin (col. 3, lines 10-30 and see the detail section for the filter system embodiments). Although, Ambrisco et al. fail to disclose the thickness of the coating as claimed. Ding et al. (5,879,697) disclose a drug-releasing coating, the coating is applied depending upon the coating thickness desired and the purpose of adjusting the thickness of the coating is for time control and release the drug (col. 8, line 52 to col. 9, line 6). Therefore, it would have been obvious to one having ordinary skill in the art to apply the coating on the filter as disclosed by Ambrisco et al. such that the coating within the range as claimed in order to control and release the drug at a desired level.

In regard to hydrogel or hydrophilic materials, it is well known to provide a layer including a hydrophilic polymer or hydrogel for control and release drug (See competent documentary evidence, Thompson et al. reference, col. 8). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made

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to employ a hydrophilic polymer or hydrogel layer into Ambrisco et al. in view of Ding et al. in order to provide a better control and release non thrombogenic material.

In regard to claim 12, a Product-by-Process claim, this claim is not limited to the manipulations of the recited steps.

Note: "laminate construction" does not impose any structural limitations on the claims distinguishable over the device of Ambrisco in view Ding et al.. Examiner considers a filter having laminate construction being a filter with two or more layers that are attached to each other, since the filter membrane and the coating attached to each other it meets the laminate construction limitation.

4. Claims 1-31, 48-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniel et al. (6,171,327) in view of Thompson et al. (5,834,449) further in view of Ding et al. (5,879,697). Daniel et al. disclose a filter as claimed except for a presence of the thickness of the coating as claimed and coating including hydrophilic or hydrogel material. Thompson et al. teach a coating layer including hydrophilic materials for use in control and release drug on a medical device such as filter (col. 8). Hydrogel is a well-known hydrophilic material for use in control and release drug on medical surface. Ding et al. teach a drug-releasing coating wherein the coating is applied depending upon the coating thickness desired and the purpose of adjusting the thickness of the coating is for time control and release the drug (col. 8, line 52 to col. 9, line 6). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the material disclose by Thompson et al. or hydrogel and adjusting the

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thickness of the coating in order to control and release the non thrombogenic material or drug a desired level. Doing so would meet all the limitation as claimed.

***Allowable Subject Matter***

5. Claims 32-41, 63 allowed. The prior art fails to disclose or suggest a filter body having regions of at least one of varying hardness and stiffness resulting at least in part from a laminate construction of at least one of the regions.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is (703) 306-3421. The examiner can normally be reached on MULTIFLEX Mon. to Sat.. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANHTUAN or NGUYEN can be reached on 703-308-2154. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system.



(Jackie) Tan-Uyen T. Ho  
Patent Examiner  
Art Unit 3731

October 12, 2004